REMARKS

Claims 1-3, 5, 7-12, 14-42 are pending. Claims 1, 15, 33-36, and 40 are amended. Claim 4 is cancelled. The subject matter of original claim 4 is now incorporated in independent claims 1 and 33. Support for the claim amendments is found in paragraph [0140] of the specification. Claims 6, 13, and 27 were cancelled previously. Claim 42 is new. Support for new claim 42 is found in paragraph [0137]. No new matter is presented.

Applicant thanks the Examiner for pointing out the objections to claims 33-36 and 40. The claim amendments have been made. Thus, the objections should be withdrawn.

In the art of medical databases, a longstanding problem when correlating adverse drug effects is reducing the "surrounding background 'noise'." Background noise is responsible for obscuring connections among data elements. (See specification, paragraph [0137].) The claimed invention resolves this problem by selecting a substance of interest, inputting data from various commonly used adverse drug effects reporting databases such as the U.S. FDA's Adverse Event Reporting System (AERS) or Medical Dictionary for Regulatory Activities (MedDRA), cleaning the data, and profiling the cleaned data. The claimed profiler can compare aspects of the target drug with "concomitant drugs," a concomitant drug being a drug that may or may not be suspected of causing a bad reaction for a patient reported in one of the adverse reporting databases. (See specification, paragraph [0123].) Until applicant made the claimed invention, other efforts at reducing "background noise" as disclosed in applicant's specification were unsuccessful because raw data from adverse effects reporting databases included an overload of verbatim information. Previous attempts at removing verbatim information failed because data was not "cleaned" sufficiently before mining the data. Insufficient cleaning resulted in poor or inaccurate analysis of a drug's effects.

Claims 15-19 and 21 are rejected under 35 USC 102(b) as being anticipated by Szarfman. Applicant disagrees. Szarfman fails to disclose all the elements of the claims, and Applicant does not acquiesce to any statements in support of the 102(b) rejection. Amended claim 15

clarifies that the claimed invention maintains a consistent vocabulary, thus reducing or eliminating the verbatim information problem as described in the preceding paragraphs.

Amended claim 15 now recites a method for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest, in part, comprising "maintaining a consistent vocabulary by processing a vector comprising a plurality of categorical terms," "wherein the plurality of categorical terms are therapeutic categories."

Szarfman fails to teach the claim limitations. Instead, Szarfman merely teaches "a derived database of signal scores." (See Szarfman, page 39.) Szarfman teaches a database of all distinct counts of event and drug combinations. (See Szarfman, page 33.) However, nowhere does Szarfman teach maintaining a consistent vocabulary by processing a vector comprising a plurality of categorical terms.

An advantage of the claimed invention is that it can maintain a consistent vocabulary for categorical terms by removing the "background noise" from the raw data contained in the U.S. FDA's Adverse Event Reporting System (AERS) or Medical Dictionary for Regulatory Activities (MedDRA). (See specification, paragraph [0140].) The claimed invention permits the sorting, comparing, and handling of thousands of cases, which was not available in the prior art. (See specification, paragraph [0140].) Since Szarfman fails to teach all of the elements of claim 15, the rejection under 35 USC 102(b) should be withdrawn. Thus, claim 15 is allowable.

Claims 1-5, 7-12, 14, 20, 22-26, 28-30, 32-35, and 38-41 are rejected under 35 USC 103(a) as being unpatentable over Szarfman and Classen, U.S. Patent No. 6,219,674. The rejection of claim 4 is moot in light of its cancellation. The subject matter of claim 4 is now incorporated in amended claim 1. Applicant respectfully disagrees with the rejection of claims 1-3, 5, 7-12, 14, 20, 22-26, 28-30, 32-35, and 38-41 for the following reasons.

Amended claim 1 recites a system for assessing and analyzing risks of adverse effects resulting from use of at least one substance of interest, in part, comprising, "at least one data mining engine," wherein "the data mining engine is a correlator to look for correlated signal

characteristics in at least one of drug information, reaction information and demographic information," "the correlator is configured to maintain a consistent vocabulary by processing a vector comprising a plurality of categorical terms," and "the plurality of categorical terms sent to the correlator are therapeutic categories."

Neither Szarfman nor Classen discloses or suggests the claimed correlator. Instead, Szarfman's database only produces a signal score. (See Szarfman, page 32.) The signal scores disclosed in Classen are merely for ranking purposes. (See Szarfman, page 44.) Szarfman discloses ranking the symptoms of an illness based on the number of times that the symptoms occur. (See Szarfman, page 46.) At page 46 of Szarfman, the reference merely discloses counting the number of adverse event reports in which particular symptoms were recorded in available databases. On the other hand, Classen is directed to a method for producing medical data labeling from information contained in adverse event databases. (See Classen, col. 8, lines 38-43.) Classen supposedly enhances the safety of medical or non-medical products. (See Classen, Abstract.) However, there is no disclosure or suggestion of the claimed correlator, as recited in amended claim 1, in either Szarfman or Classen, or any combination thereof.

An advantage of the claimed invention as recited in amended claim 1 is that the correlator reduces background noise that is responsible for obscuring connections among data elements. (See specification, paragraph [0135]. The correlation performed by the claimed correlator is applied after filtering, "greatly enhancing the signal and reducing noise." (See specification, paragraph [0137]. As the specification explains, the claimed correlator involves product moment correlation typically only used for number analysis. (See specification, paragraph [0139]. In this case, the claimed correlator is not primarily for correlating numbers. Instead, the claimed correlator is capable of correlating categorical terms in a "new and previously unexplored use of the Pearson R^2." (See specification, paragraph [0137].)

Claim 1 also recites "assessment of a substance of interest in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements."

In the Office Action, the Examiner points to col. 5, lines 10-18, suggesting that Classen discloses assessment of a substance of interest in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements. (See Office Action, page 5.) This is improper. Classen merely discloses consulting resources that contain one of two categories: 1) medical products or 2) so-called "non-medical products," such as foods, food additives, beverages, vitamins, alcohol, tobacco, cosmetics, mechanical devices and children's toys, personal and household cleaning products, and other chemicals. (See Classen, col. 5, lines 4-16.) Disclosing two product categories is not the same as or obviously similar to assessing a substance of interest in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements.

For all of the reasons stated above, neither Classen nor Szarfman, or any combination thereof, discloses or suggests the claimed invention. Moreover, no combination of Szarfman and Classen would have resulted in the claimed invention. Therefore, the rejection under 35 USC 103(a) should not stand.

Independent claim 33 is amended to recite substantially similar subject matter as claim 1. Thus, amended claim 33 is allowable. Claims 34 to 42 are allowable at least due to their dependency from claim 33.

New claim 42 recites the use of the Pearson product-moment correlation, as explained in paragraph [0137] of Applicant's specification.

Early action soliciting allowance of claims 1-3, 5, 7-12, 14-26, and 28-42 is requested.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. **597932000700**.

Respectfully submitted,

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